



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 10 1997

Alexis Gambetta
Chief Executive Officer
HealthMark
4700 East Iliff Avenue
Denver, Colorado 80222-6025

0777 '97 DEC 16 P1:39

Dear Ms. Gambetta:

This is in response to your letter of October 1, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that HealthMark is making a number of claims for "Herbal Dietary Supplement Standardized Potency Echinacea." These claims, among other things, state that the product is for "Increased Natural Resistance to Seasonal health Problems" and is "...an especially popular dietary supplement during the cold and flue season and is often recommended by health care specialists."

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, taken together, suggest that it is intended to treat or prevent a disease, namely cold and flu. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also contained a label for a Multiple Vitamin/Mineral with Iron dietary supplement, which contains 7.5 milligrams (mg) iron per recommended dosage. We would like to note that in the January 15, 1997 Federal Register (62 FR 2218; enclosed), FDA published a final regulation requiring a label warning statement on products taken in solid oral dosage form to supplement the dietary intake of iron. Your product label does not contain the label warning statement required by 21 CFR 101.17. A dietary supplement in solid oral dosage form that contains added iron, that enters interstate commerce after the effective date for implementation of this regulation (July 15, 1997), and that does not bear the required warning statement on its label or in its labeling, is misbranded under sections 403(a)(1) and 201(n) of the act.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240



October 1, 1997 0778



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Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
"C" Street SW (HFS-455)
Washington, D.C. 20204

To Whom It May Concern:

Enclosed please find labels for vitamins that HealthMark is marketing. As per FDA guidelines, I am informing you within 30 days after first marketing a statement of nutritional support.

Should you need any further information, please do not hesitate to contact us.

Sincerely,

Alexis Gambetta
Chief Executive Officer

/ag

cc: Dr. Robert Gleser - HealthMark
Dr. Mitchell Gershten - HealthMark
Dr. Wayne Peters - HealthMark

HealthMark

A Center For Integrated Healing

4700 East Iliff Avenue
Denver, CO 80222-6025
(303) 584-8900
Fax: (303) 584-0525

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RECOMMENDATIONS

As a dietary supplement for adults, take one capsule daily as recommended by your health care practitioner or nutritional counselor.

Each Capsule Contains:

NUTRIENT	SOURCE	POTENCY	%USDA*
Vitamin A (acetate, beta carotene)		7,500 IU	150
Vitamin B1 (thiamine HCl)		5.5 mg	367
Vitamin B2 (riboflavin)		5 mg	200
Vitamin B3 (niacin & inositol niacinate)		30 mg	150
Vitamin B5 (calcium pantothenate)		35 mg	350
Vitamin B6 (pyridoxine HCl)		10 mg	500
Vitamin B12 (cyanocobalamin)		30 mcg	500
Folic Acid		200 mcg	50
Biotin		100 mcg	33
Vitamin C (ascorbic acid)		250 mg	417
Vitamin D3		100 IU	25
Vitamin E (acetate)		100 IU	333

Distributed by: HealthMark Centers, L.L.C.

A Center for Integrated Healing™

4700 East Iliff Avenue

Denver, Colorado, USA 80222

Q.C.#

(303) 584-8900

EXPIRATION:



Dietary Supplement

MULTIPLE VITAMIN/MINERAL with IRON

60 Capsules (775 mg.)

HealthMark
A Center For Integrated Healing

NUTRIENT	SOURCE	POTENCY	%USDA*
Zinc (polynicotinate)		7.5 mg	53
Copper (aspartate)		1000 mcg	50
Manganese (aspartate)		3 mg	30
Chromium (picolinate)		100 mcg	500
Selenium (polynicotinate)		50 mcg	70
Iodine		75 mcg	53
Iron (aspartate)		7.5 mg	33
Boron (citrate/aspartate/xyly)		500 mcg	50
Vanadium (aspartate)		5 mcg	10
Molybdenum (aspartate)		30 mcg	30

*Recommended Daily Allowance

**No USDA established for this nutrient. In a base of natural excipients including vegetable phytonutrients.

Store in a cool, dry place away from sunlight and moisture. Do Not Consume If You Are Pregnant, Lactating, On Medication, Have A Medical Condition Or Under A Physicians Care Without First Consulting Your Doctor. Keep Out Of Reach Of Children.

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RECOMMENDATIONS:

As a dietary supplement for adults, take one or two capsules twice daily or as recommended by your health care practitioner. For best results, use for no more than 7 - 10 days.

CONTENTS:

Echinacea concentrated root extract (angustifolia and purpurea) standardized to 4% total phenolic compounds, natural excipients. Store in a cool, dry place away from sunlight and moisture.

Do not consume if you are pregnant, lactating, on medication, have a medical condition or under a physician's care without first consulting your doctor.

Distributed by: HealthMark™ Inc.
A Center for Integrated Healing.
4700 East Iliff Avenue, Denver,
Colorado, USA 80222. (303) 584-8900.

Q.C.#

EXPIRATION:



Herbal Dietary Supplement
Standardized Potency

ECHINACEA

(Echinacea purpurea and angustifolia)
Increased Natural Resistance to Seasonal Health Problems*

60 Capsules (130 mg. each)

HealthMark
A Center For Integrated Healing

Echinacea extract has been the subject of intensive scientific investigation worldwide. This unique botanical extract enhances the body's natural resistance.* It has become an especially popular dietary supplement during the cold and flu season and is often recommended by health care specialists. HealthMark™ Echinacea is a pure, natural botanical extract which is standardized to assure quality and consistency.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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